The opinion in support of the decision being entered today was ***not*** written for publication and is ***not*** binding precedent of the Board.

Paper No. 24

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARK E. CONNELL, ROBERT A. BEDIENT, RAYMOND ELSEN, MICHAEL E. HOGARD, HARLEY D. JOHNSON, THOMAS D. KELLY, JEAN MCEVOY LONG, BRUCE A. PETERSON, WILLIAM G. PRESTON, JR. and DALIBOR J. SMEJTEK

Appeal No. 2003-0235
Application 09/711,240

ON BRIEF

Before PAK, WARREN and KRATZ, *Administrative Patent Judges*.

WARREN, *Administrative Patent Judge*.

Decision on Appeal

This is an appeal under 35 U.S.C. § 134 from the decision of the examiner finally rejecting claims 30 through 41, all of the claims in the application. Claims 30 through 32 are illustrative of the claims on appeal:

30. A hemodialysis apparatus, comprising:

(a) means for delivering extracorporeal blood to a hemodialyzer and for controlling at least one extracorporeal-blood parameter selected from the group consisting of (i) blood-flow rate, (ii) arterial pressure, (iii) venous pressure, and (iv) anticoagulant delivery to the extracorporeal blood; and

(b) a user/machine interface operably connected to said means for delivering extracorporeal blood, the user/machine interface comprising a touch screen adapted to display an indicium corresponding to a parameter pertinent to operation of the hemodialysis machine and to permit the user, by touching the indicium, to cause a change in the parameter.

31. A hemodialysis apparatus, comprising:

(a) a dialysate-delivery system for supplying dialysate to a hemodialyzer, the dialysate-delivery system comprising at least one unit selected from the group consisting of (i) a dialysate preparation unit, (ii) a dialysate-circulation unit, (iii) an ultrafiltrate-removal unit, and (iv) a dialysate-monitoring unit; and

(b) a user/machine interface operably connected to the dialysate-delivery system, the user/machine interface comprising a touch screen adapted to display an indicium corresponding to a parameter pertinent to operation of the hemodialysis machine and to permit the user, by touching the indicium, to cause a change in the parameter.

32. A hemodialysis apparatus, comprising:

(a) a dialysate-delivery system connectable to a hemodialyzer for supplying dialysate to a hemodialyzer, the dialysate-delivery system comprising at least one unit selected from the group consisting of (i) a dialysate preparation unit, (ii) a dialysate-circulation unit, (iii) an ultrafiltrate-removal unit, and (iv) a dialysate-monitoring unit;

(b) an extracorporeal blood-delivery system connectable to the hemodialyzer for routing extracorporeal blood to the hemodialyzer in coordination with the dialysate-delivery system, the extracorporeal blood-delivery system comprising at least one unit selected from a group consisting of (i) a blood-circulating unit, and (ii) a blood-monitoring unit;

(c) a controller connected to and controllably operating the dialysate-delivery system and the extracorporeal blood-delivery system; and

(d) a touch screen connected to the controller, the touch screen adapted to display an indicium corresponding to a parameter pertinent to operation of the hemodialysis apparatus and to permit a user, by touching the indicium, to cause a change in the parameter.

The appealed claims, as represented by the above claims, are drawn to a hemodialysis apparatus comprising at least a user/machine interface operably connected, including through a controller, to means for delivering extracorporeal blood to a hemodialyzer, at least a unit of a dialysate-delivery system and/or at least a unit of an extracorporeal blood-delivery system, and comprising at least one indicium corresponding to a parameter pertinent to the operation of said means and/or of the units of systems displayed on a touch screen, thus permitting the user to cause a change in the parameter by touching the indicium on that screen.

The references relied on by the examiner are:

Lichtenstein et al. (Lichtenstein)	4,370,983	Feb. 1, 1983
Kerns et al. (Kerns)	4,756,706	Jul. 12, 1988
Rubalcaba, Jr. (Rubalcaba)	4,898,578	Feb. 6, 1990

The examiner has rejected appealed claims 30 through 41 under 35 U.S.C. § 103(a) as being unpatentable over Lichtenstein in view of Rubalcaba and/or Kerns.

Appellants state in their brief (page 3) that appealed claims are separately patentable based on dependency relationships (page 4). Thus, we decide this appeal based on appealed claims 30 through 34, 37, 40 and 41. 37 CFR § 1.192(c)(7) (2002).

We affirm.

Rather than reiterate the respective positions advanced by the examiner and appellants, we refer to the examiner's answer and to appellants' brief and reply brief for a complete exposition thereof.

Opinion

Our review of the application of the applied prior art to the claimed apparatus encompassed by appealed claims 30 through 34, 37, 40 and 41 by the examiner requires that we first interpret the language thereof by giving the claim terms their broadest reasonable interpretation in light of the written description in the specification as it would be interpreted by one of ordinary skill in this art, including the meaning for claim terms established in the written description in the specification. *See, e.g., In re Hyatt,* 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000); *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997), *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). We determine that in each of the appealed claims, the claimed hemodialysis apparatus comprises at least a user/machine interface which comprises at least a touch screen, a simple input/output device for a computer, operably connected through computer software to means for delivering extracorporeal blood to a hemodialyzer, a dialysate-delivery system and/or an extracorporeal blood-delivery system, each of which consists of or comprises at least one specified controllable parameter or unit. The touch screen input/output device displays an indicium as well as information corresponding to a parameter pertinent to the operation of the hemodialysis

apparatus through computer software, thus permitting the user to cause a computer controlled change in that parameter by touching the indicium, including changing a setting in that parameter in the computer. The transitional term "comprising" opens the claims to any manner of hemodialysis apparatus that includes the specified touch screen operably connected thereto along with specified system means and units, without regard to the configuration of the apparatus. *See generally, In re Baxter*, 656 F.2d 679, 686-87, 210 USPQ 795, 802-03 (CCPA 1981) ("As long as one of the monomers in the reaction is propylene, any other monomer may be present, because the term 'comprises' permits the *inclusion* of other steps, elements, or materials.").

In other words, the appealed claims encompass a hemodialysis apparatus in which at least one parameter of the apparatus, that can involve one of the specified patient parameters or system means or units, is controlled by a computer having at least one touch screen as the input/output user/machine interface, that is operably connected to the means and units of the apparatus without limitation as to its location relative to any other component(s) of the apparatus. The parameter is pertinent to the operation of said means and/or units of the apparatus and can be changed, that is, controlled by software, by a user touching an indicium on the touch screen input/output device that corresponding to the appropriate parameter in the software, including changing a setting with respect thereto.

The only apparatus components specified are the recited touch screen input/output device, which can be connected to a controller, and the means and/or units of the apparatus, and there is no limitation on the manner in which the apparatus is configured or a computer and its software operates either *per se*, with respect to the touch screen input/output device, or with respect to the individual means and/or units of the apparatus. Indeed, in this respect, appellants state in the written description of the specification with respect to the computer, its software and touch screen input/output device user interface that

> [t]ouch screens are known in the art and are commercially available from a number of sources . . . The use of touch screens in user interface applications for medical equipment is also known, as shown for example in [Rubalcaba] . . . , the disclosures of which [is] . . . incorporated herein by reference.
>
> In the prior art, as illustrated by the above-referenced patents, touch screens have been used in conjunction with computers and CRTs to provide a control panel that can be changed under computer control. The means by which a computer, a CRT, and a

touch screen can be cooperatively operated in this fashion is well known and does not, per se, form a part of this invention. [Page 13, line 31, to page 14, line 7.]

Turning now to the ground of rejection of appealed claims 30 through 34, 37, 40 and 41 under § 103(a), we have carefully reviewed the record on this appeal and based thereon find ourselves in agreement with the supported position advanced by the examiner (answer, pages 5-7) that, *prima facie*, one of ordinary skill in this art would have found in the combined teachings of Lichtenstein, Rubalcaba and Kerns the reasonable suggestion that a touch screen input/output device can be used with a computer operating a hemodialysis apparatus disclosed in Lichtenstein as shown by Rubalcaba and Kerns in the reasonable expectation that the operator of the apparatus can control at least one parameter pertinent to the operation of that system through the computer using the touch screen input/output device. We add the following to the examiner's analysis for emphasis.

We find that Lichtenstein would have disclosed to one of ordinary skill in this art[1] the computerized monitoring and control of the withdrawal, infusion and/or extracorporeal circulation of a fluid from and/or to a patient using apparatuses with modular components, including apparatuses for hemodialysis and the infusion of medications (e.g., abstract, col. 2, line 41, to col. 4, line 17, particularly col. 4, lines 3-17, cols. 9-18, and cols. 28-32). The data with respect to adjusting patient and system parameters obtained from sensors in the modules by the computer software can be processed and displayed to the user by an appropriate display, such as an output device including CRT which would have been expected by one of ordinary skill in this art to function in connection with an input device, such as a so-called "mouse," for the adjustment of adjustable valves and pump and other aspects of the modules in order to adjust one or more patient and/or system parameters (e.g., col. 6, lines 40-60, col. 8, lines 1-16 and 30-34, col. 28, lines 60-65, and col. 32, lines 53-62). As the examiner points out, Lichtenstein does not disclose a touch screen as an input/output device with the disclosed systems.

[1] It is well settled that a reference stands for all of the specific teachings thereof as well as the inferences one of ordinary skill in this art would have reasonably been expected to draw therefrom, see *In re Fritch*, 972 F.2d 1260, 1264-65, 23 USPQ2d 1780, 1782-83 (Fed. Cir. 1992); *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968), presuming skill on the part of this person. *In re Sovish*, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985).

In the passage from the specification that we quoted above, appellants acknowledge that the use of a touch screen as an input/output device functioning as an information and control panel in the computerized control of medical equipment was known in the prior art, citing, *inter alia*, Rubalcaba in this respect. *See generally, In re Nomiya*, 509 F.2d 566, 570-71, 571 n.5, 184 USPQ 607, 611, 611 n.4 (CCPA 1975). We find that Rubalcaba acknowledges prior art centrally managed drug delivery systems capable of multiple infusions in a patient which comprises computer control of infusion pump modules wherein the user receives information and inputs data by touching an indicium on a touch screen input/output device with respect to at least one parameter pertinent to the operation of the apparatus. Rubalcaba discloses an improvement thereon in which the computer manipulation of parameter values for each infusion pump module is enhanced with the view toward reducing user confusion and error, such as with respect to crisis and patent reaction management (e.g., col. 1, lines 20-28, col. 2, lines 7-62, and col. 8, lines 35-45; **Figs. 1-9**).

We further find that Kerns discloses a centrally managed drug delivery system capable of multiple infusions in a patient which comprises computer control of a modular infusion pump system wherein the user receives information and inputs data, including settings, with respect to patient and system parameters pertinent to the operation of the system, by touching an indicium on a touch screen input/output device with respect to at least one parameter pertinent to the operation of the apparatus (e.g., col. 1, line 41, to col. 2, line 13, col. 2, line 45, to col. 7, line 45, and col. 8, line 48, to col. 12, line 2; **FIGs. 1, 2a** and **7-17**) of the type acknowledged by Rubalcaba.

Based on this substantial evidence, we determine that, *prima facie*, one of ordinary skill in this art routinely following the combined teachings of Lichtenstein, Rubalcaba and Kerns would have employed a touch screen input/output device to facilitate computer control of the modular hemodialysis apparatus of Lichtenstein, which involves infusion, in the reasonable expectation of enhancing user control of at least one of the patient and system parameters pertinent to the operation of that apparatus as shown in by Rubalcaba and Kerns in analogous infusion apparatuses. Thus, this person would have reasonably arrived at the claimed hemodialysis apparatus encompassed by appealed claims 30 through 34, 37, 40 and 41, including

each and every limitation thereof arranged as required therein, without recourse to appellants' specification. *See, e.g., Pro-Mold & Tool Co. v. Great lakes Plastics Inc.*, 75 F.3d 1568, 1573, 37 USPQ 1626, 1629-30 (Fed. Cir. 1996) ("In this case, the reason to combine [the references] arose from the very nature of the subject matter involved, the size of the card intended to be enclosed."); *In re Gorman*, 933 F.2d 982, 986-87, 18 USPQ2d 1885, 1888-89 (Fed. Cir. 1991) ("The extent to which such suggestion [to select elements of various teachings in order to form the claimed invention] must be explicit in, or may be fairly inferred from, the references, is decided on the facts of each case, in light of the prior art and its relationship to the applicant's invention."); *In re Dow Chem. Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988) ("The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that [the claimed process] should be carried out and would have a reasonable likelihood of success viewed in light of the prior art. [Citations omitted] Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure."); *Sovish*, 769 F.2d at 743, 226 USPQ at 774 (In evaluating the relevance of the various teachings of the references, we must presume skill on the part of those of ordinary skill in this art.); *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981)("The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art."); *see also In re O'Farrell*, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1680-81 (Fed. Cir. 1988) ("Obviousness does not require absolute predictability of success. . . . There is always at least a possibility of unexpected results, that would then provide an objective basis for showing that the invention, although apparently obvious, was in law nonobvious. [Citations omitted.] For obviousness under § 103, all that is required is a reasonable expectation of success. [Citations omitted.]").

Accordingly, since a *prima facie* case of obviousness has been established over the combined teachings of Lichtenstein, Rubalcaba and Kerns, we have again evaluated all of the evidence of obviousness and nonobviousness based on the record as a whole, giving due consideration to the weight of appellants' arguments in the brief and reply brief and the evidence

in the submitted declaration of Dr. Sadler under 37 CFR § 1.132 (2002) (Sadler declaration)[2] and other evidence as relied on in the brief and reply brief. *See generally, In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Johnson*, 747 F.2d 1456, 1460, 223 USPQ 1260, 1263 (Fed. Cir. 1984); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984); *In re Fielder*, 471 F.2d 640, 642-43, 176 USPQ 300, 302 (CCPA 1973).

We agree with the examiner's response (answer, pages 7-10) to appellants' arguments in the brief (pages 5-11) with respect to the *prima facie* case of obviousness, to which we add the following for emphasis. We appreciate the difference in the fluids that are infused into a patient by a hemodialysis apparatus as disclosed in Lichtenstein and a drug delivery apparatus as disclosed by each of Rubalcaba and Kerns. However, one of ordinary skill in this art would have known from the disclosure of Lichtenstein that the modular apparatuses disclosed therein are useful for hemodialysis and for drug delivery as we have pointed out above, and both Rubalcaba and Kerns disclose the effectiveness of using a touch screen input/output device for enhanced user control in computerized modular drug delivery apparatuses. Thus, from a number of perspectives, the use of a touch screen input/output device for computer control purposes in both types of modular apparatuses used for medical purposes in similar manner would have been readily suggested to one of ordinary skill in this art by the very nature of the apparatuses and the known attributes of a touch screen input/output device user interface with respect to such apparatuses, *see, e.g., Pro-Mold, supra*; *Keller, supra*, and indeed, both Rubalcaba and Kerns constitute analogous prior art under either test set forth in *In re Clay*, 966 F.2d at 659-60, 23 USPQ2d at 1060-61 (Fed. Cir. 1992).

We are also unconvinced by appellants' arguments based on the hardware and software involved with touch screen input/output devices and computer control of an apparatus since none of the appealed claims specify any hardware and/or software limitations in this respect as we have interpreted them above, pointing out that appellants make clear in the written description in

[2] The Sadler declaration was submitted in a separate document with the brief on September 16, 2002, but not separately entered in the filewrapper (see Paper No. 15). The examiner entered this submission of evidence after appeal as set forth in the answer (page 11). *See* 37 CFR § 1.195 (2002).

the specification that matters of interaction between a touch screen input/output device and other computer hardware as well as software do not form a part of the disclosed invention. With respect to the control of a patient and system parameter pertinent to the operation of the apparatus, the development of control software, including software for the input and output of information on the touch screen input/output device with respect to the pertinent parameter would have been within the ordinary skill in this art in view of the teachings of the applied references, and there is no claim limitation in this respect as we interpreted the appealed claims above. In any event, we interpreted all of the appealed claims to require only computer control of one parameter associated with a hemodialysis apparatus, system or patient, with a touch screen input/output device, and the applied references certainly supply substantial evidence establishing the requisite motivation and expectation of success to satisfy all of the limitations of the appealed claims. Indeed, in this respect, appellants' arguments for the separate patentability of the appealed claims based on different limitations appearing therein, set forth in the brief (pages 17-20), have been shown by the examiner to be satisfied by the applied prior art (answer, e.g., pages 6-7), and we found this to be so above as well.

The thrust of the arguments submitted by appellants in the reply brief (pages 1-3) is the same as the arguments presented in the brief, and upon consideration thereof, we remain unconvinced for the reasons we have set forth with respect to the arguments in the brief.

Turning now to the objective evidence of nonobviousness, we have considered such evidence to the extent that it is relied on by appellants in the brief (pages 11-17) and reply brief (pages 4-6). The evidence is the Sadler declaration and four publications (brief, pages 13-16). We fail to find in the filewrapper any evidence that appellants have made any of the four publications of record in this application, and thus reliance thereon in argument in the brief is improper. 37 CFR § 1.192(c)(8) (2002). Ordinarily, that would end the matter with respect to the four publications. However, the examiner points out that the four publication are of record in parent application 09/067,922 and has considered appellants' arguments with respect to these documents (answer, page 11), and indeed, the documents were submitted with the amendment of October 7, 1999 in that application (Paper No. 10). Thus, in this instance, we will consider the

four publications in the interest of judicial economy. Appellants should make the four publications of record in the present application in order to complete the record.

Accordingly, in addition to the Sadler declaration we have considered, as cited by appellants: *International Design 1991 Annual Design Review*, pages 61, 64 and 65 (*International Design*); Young, "Dialysis, Gently," *Business Week*, June 17, 1991, page 78 (*Business Week*); "Dialysis Machine Speeds Treatment and Repairs," *Wall Street Journal*, May 20, 1991 (*Wall Street Journal*); and, "Althin CD Medical Wins Design Award for Dialysis Machine," *Nephrology News & Issues*, July 1991, page 27 (*Nephrology News & Issues*).

The issue here is whether the testimonial and documentary evidence adduced by appellants evinces (1) commercial success, long-felt need and/or copying by others of a hemodialysis apparatus that includes a touch screen as encompassed by the appealed claims, and (2) a sufficient nexus therebetween and the presence of the touch screen *per se*. *See, e.g.*, *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1359-60, 51 USPQ2d 1385, 1400 (Fed. Cir. 1999); *Gambro Lundia AB v. Baxter healthcare Corp.*, 110 F.3d 1573, 1579, 42 USPQ2d 1378, 1384 (Fed. Cir. 1997); *In re Huang*, 100 F.3d 135, 139-140, 40 USPQ2d 1685, 1689-90 (Fed. Cir. 1996); *Demaco Corp. v. F. Von Langsdorff Licensing, Ltd.*, 851 F.2d 1387, 1391-94, 7 USPQ2d 1222, 1225-28 (Fed. Cir. 1988); *In re Fielder*, 471 F.2d 640, 646, 176 USPQ 300, 305 (CCPA 1973).

We essentially agree with the examiner's responses (answer, pages 10-14) to appellants' arguments with respect to the evidence in the brief (pages 11-17). We add the following to the examiner's analysis. We find from Dr. Sadler's testimony in his declaration (declaration) that at the time the declaration was executed, September 29, 1999, he was a paid consultant of Althin Medical, Inc. (Althin), but states that he "received no direct financial or other economic benefit from sales of the System 1000 [Dialysis Delivery System]" (¶ 8.), manufactured by Althin (¶ 6.). The System 1000, also called the Drake Willock System 1000 Dialysis Machine in *International Design*, *Business Week* and *Nephrology News & Issues*, is the hemodialysis apparatus that is the evidentiary basis for appellants' case for commercial success, long felt need and copying by others (*see* declaration ¶ 7; brief, page 12). Althin is the past assignee of the present application, and other related applications, several now issued, including application 09/067,922, now

abandoned, in which the Sadler declaration was originally submitted (declaration ¶ 7), all of which were assigned to Baxter International on December 19, 2000, according to assignment records of the USPTO.

Dr. Sadler testifies that "[t]he key feature of the System 1000 is its touch screen" which "replaces a number of necessary electromechanical moving parts and control mechanisms (such as switches, buttons, and dials) of hemodialysis machines" which were "prone to malfunction and needed regular replacement," thus eliminating "many sources of malfunction inherent in other hemodialysis machines existing at the time the System 1000 made its commercial debut" (¶ 10.); that "the touch screen of the System 1000 is capable of displaying more information than its contemporary competitor instruments" and "the information display on the touch screen of the System 1000 can be changed by changing screens" (¶ 11.); that "the touch screen of the System 1000 is surprisingly intuitive in its use," the user requiring "very little training to be proficient in its use," pointing to a situation in which only a short period for training was available which he does "not believe . . .could have [been] accomplished . . . with any other hemodialysis machine available at the time . . . [which] (lacking a touch screen) . . . generally require several hours of training, including about one to three days with a training nurse on-site who instructs and helps solve problems" (¶ 12).

Dr. Sadler further testifies that "[w]hile almost all hemodialysis machines use microprocessors, the System 1000 was the first to employ a complete computer, including a motherboard" making it "easy to program (using the touch screen) and has proved to be surprisingly stable and reliable" (¶ 13).

Thus, Dr. Sadler concludes that "the touch screen represents an important and substantial technical advancement in hemodialysis machined technology, especially when viewed in light of other hemodialysis machines available at the time the System 1000 made its debut" (¶ 13). Dr. Sadler knows of "no other hemodialysis machine that was manufactured with a touch screen prior to the System 1000" and states that the other screens "used . . . to display data and error functions, such screens were much different than the touch screen of the System 1000 because they could not be used to control the machine itself" (¶ 16).

Dr. Sadler further believes that "other unique and innovative features of the System 1000 include: (a) its tall and slender profile . . . ; (b) its smooth surface, which prevents liquids from seeping into the machine, a common cause of malfunction in other hemodialysis machines; (c) the placement and layout of blood tubing is so obvious that instruction is not necessary – an operator can intuitive know how blood tubing should be placed by simply looking at the machine; (d) the clamp that holds the dialyzer was cleverly designed and remains better than similar clamps on other hemodialysis machines; and (e) the design allows easy maintenance and servicing" (¶ 14).

Dr. Sadler states that he believes that "the System 1000 is the most innovative hemodialysis machine developed in the past fifteen years and one of the most innovative pieces of medical instrumentation I have seen in my career" (¶ 9.), and points out that during 1982 to the time the declaration was executed, he served in number of positions in which he "used, examined, tested or reviewed more than 12 different hemodialysis machines from at least seven different manufactures" (¶¶ 3-6.); that "[w]hile other manufactures have tried to develop a hemodialysis machine that is simple to use, reliable, and easy to maintain, I believe the System 1000 remains the state of the art in the hemodialysis machines today, even though it first appeared almost ten years ago" (¶ 15); and that "[a]t the time the System 1000 was released, it represented a truly novel and surprisingly innovative development in the market of hemodialysis machines" and that "virtually every competitor of Althin has developed . . . a respective hemodialysis machine that includes many of the innovations that first appeared in the System 1000" (¶ 17).

We find from each of the four articles that the Drake Willock System 1000 Dialysis Machine which Dr. Sadler extols the attributes of, is in large measure, the design work of Ziba Design of Portland, Oregon (Ziba). The *International Design* article reports that three jurors selected the Drake Willock System 1000 Dialysis Machine as a "co-Best of Category products" because "'the designers did more than hit the high points – they brought a new dimension of value to their clients' products'" in "human terms as well as against the bottom line" as "'[t]he design process has significantly improved the safety and productivity of the users of these products" (page 61). A photograph of the front of the System 1000 and a photographic of

apparently the back of the machine is included (page 65). Specifically, "the System 1000's appearance was considered by the jurors to be least among its numerous merits," which "numerous merits" apparently include the following:

> Dialysis is an extremely invasive medical procedure in which a patient is connected by means of surgical hoses to a machine that pumps and cleans his blood. The patient remains connected to the machine for long periods of time, as his blood circulates between his body and the machine. Therefore, one of the most complex aspects of a dialysis machine is the placement and organization of the bloodlines that route the patient's blood from the body, though the machine's filters and back again. In the System 1000, the designers reconfigured the bloodlines in such a way as to shorten them, thereby reducing the amount of blood outside the patient's body at any one time, and reducing the time required for treatment. All of the System 1000's internal components were arranged in a "single layer design" mounted at the rear of the machine, accessible by means of a simple panel. This reduced the maximum access time to serviceable parts from 30 minutes to two. Furthermore, all parts are modular and any part in need of service or replacement can be removed without affecting those surrounding it.
>
> "From a productivity standpoint," said [a juror], "this machine is outstanding. It reduced prep time by 35%, it reduced the amount of waste generated by the process by 15% and it increased useable service time." The jurors were equally impressed with the logic and simplicity of the System 1000's interaction design. A complex series of analog knobs and dials was replaced by a touch screen loaded with self-prompting software. This feature reduced the amount of training required of dialysis personnel, reduced the margin of operator error, and allowed operators to devote more time to their patients and less to the machine. "In any complex piece of equipment, it is always extremely difficult to rationalize the configuration and to find the right place for everything," [a juror] said. . . . . [page 64.]

The work of Ziba is reported in a side bar (pages 64-65).

We find praise for the design work of Ziba in each of *Business Week*, *Wall Street Journal* and *Nephrology News & Issues*, with the scope of Ziba's effort detailed by *Business Week*, noting that it started in 1998 and "took 2½ years to design [the System 1000 dialysis machine] – fast by the medical world's standards but the longest project Ziba has ever worked on." This article contains a photograph of the front of the System 1000 dialysis machine as shown in *International Design*. *Business Week* sets forth this perspective of Ziba's effort and additional attributes of the System 1000 dialysis machine:

> Few things are more terrifying than kidney dialysis machines. They're squat metal boxes covered with knobs and dials and fitted with cold metal clamps, IV poles, and snakelike rubber tubes with blood and chemicals surging through them.
>
> But . . . Ziba . . . figured out how to make one that's a lot friendlier and a lot easier to use. It's tall, white, and sleek, with a friendly touch-screen computer face, round plastic clamps, and tiny splashes of pink, blue, and yellow. The Drake Willock System 1000 is so appealing, in fact, that . . . Althin, bought its maker . . . last year, largely on the market potential of the product.
>
> . . . .
>
> Ziba wanted to make the machine easy for technicians to use while projecting a non-threatening face to patients. Its design included color-coded tube connectors, a one-handed mechanisms for raising the IV pole, and a softened shape for the clamps.
>
> . . . .
>
> In the age of AIDS, the new machine is designed with hardly any cracks or crevices to catch blood. Rounded surfaces make it easy to clean. Dials and knobs are replaced by the touch screen.
>
> The dialysis unit, as designed, can be sold in any country, since the only words it uses are in the software. It has automated self-checks and redundant safety systems, as well as self-prompting software so a technician can adjust treatment parameters easily. Even the shortest nurse can easily adjust the IV pole and clamps with just one hand. The back swings open for easy access to all moving parts, and the unit requires routine maintenance only once a year. "It's a very sophisticated machine," says Kelly proudly. Yet everything about it is easy – except, of course, the hard-fought design effort that made it so.

Nephrology News & Issues reports that recognition of Ziba's design efforts was in the form of "the 'Best of Category' [award] for the design of . . . the Drake Willock System 1000 dialysis delivery system in the 1991 *International Design* Annual Review," of which there was two such awards out of 1,304 entries, and "a gold medal from the Industrial Design Excellence Award (IDEA), sponsored by *Business Week* and conducted by Industrial Designers Society of America," apparently referring to the *Business Week* article relied on by appellants. The *Nephrology News & Issues* article contains the same photograph as in *Business Week* and *International Design*, and further reports that

> [t]he new machine was actually designed by . . . Ziba . . . The design team took 2½ years to create the system. It is much smaller than the older machine, and has features that cater both to the operator and the patient. The knobs and dials have been replaced by a touch screen. Computer software helps to reduce operator training time and error,

> and because the only words which are used are those of the software, the machine can be used worldwide. This software also has automatic self-checks and redundant safety systems. All of the corners are rounded so that clean-up and sanitation are more efficient.

The *Wall Street Journal* article, which appears to be incomplete as submitted in the file of parent application 09/067,922, refers to "[t]he other equipment best in ID's review" and states that

> Althin . . . used to make a dialysis machine that looked like something out of Flash Gordon: huge, imposing dials and knobs and lots of snaky tubing. The controls gathered germs. The machine took a long time to learn to operate. Technicians made too many errors. And long tubes meant patients had a lot of blood outside their bodies during treatment, which increased the danger of low pressure.
>
> With the help of Ziba . . . , Althin has reconfigured the machine to solve many of these problems. The new System 1000 dialysis machine is much smaller than its predecessor. It has fewer angles to catch dirt, and surfaces are rounded for easier cleaning.
>
> The knobs and dials have been replaced by a touch screen loaded with self-prompting software. This reduces operator training time and error and lets operators spend more time with the patient, less with the machine. Computerization has cut preparation time by 35%, which means a patient can spend less time on the machine or can get additional care. Or the machine can serve more patients and pay for itself faster.
>
> To reduce down time, the designers made all parts modular. Parts needing service can be popped out and quickly replaced.

Based on the above evidence, we have no doubt that System 1000 is a successful dialysis machine in terms of commercial success because it satisfied a long-felt need for a better designed dialysis machine and was copied by others because of that successful commercial design. However, we cannot subscribe to the inferences and allegations advanced by appellants based on this evidence (brief, pages 11-17; reply brief, pages 4-5), that all of the accolades and successes are solely or to a significant extent due to the presence of a touch screen *per se* as the input/output user interface device, which is the only element of a claimed hemodialysis apparatus that is specifically recited in all of the appealed claims. We recognize in this respect that certain means and/or units of the hemodialysis apparatus are specified in the appealed claims. However,

an apparatus that would be characterized as a hemodialysis apparatus would have one or more such means and/or units.

We are of the view that in this case it is not a matter of whether merely adding a touch screen input/output device *per se*, or, if necessary, a touch screen input/output device and the supporting computer hardware and software, such as a "controller," to a "Flash Gordon," clunky, old style dialysis machine, or even a computer controlled, modular dialysis machine as disclosed by Lichtenstein results in a successful machine. Indeed, the substantial changes in the old style dialysis machine made by Ziba along with others, from the use and location of modular components, rounded corners, location and length of fluid lines, clamp construction, IV pole construction and location, and backdoor access to the modules, in short the configuration of the machine, to the tailored computer hardware and software used to control the machine as error free as possible, were by far the key reasons for the notoriety and success of System 1000 as shown by the documentary evidence, none of which is encompassed by a claim limitation. There is no evidence that without the touch screen input/output device *per se*, there would have been no dialysis machine with the other attributes of the System 1000. There is also no evidence that the use of the touch screen input/output device *per se* in such context, configuration and computer control, in permitting the elimination of knobs and dials found on old style dialysis machines contributed more than a touch screen input/output device was know to do in the prior art in the configuration and computer control of infusion medical equipment, which was an input/output device for data and information that permits a compact housing design devoid of knobs and dials as shown by both Rubalcaba (e.g., **Fig. 1**, central management unit **14** and touch screen **30**, **Figs. 3-9**) and Kerns (e.g., **FIGs. 1** and **2a**, central management unit **14** and flat screen **74**, and **FIGs. 7-17**) (*see above* pp. 5-6). *Cf. Fielder, supra.*

Thus, based on the evidence in the testimony of appellants' in-house witness and the four documents with respect to the System 1000 as a whole and the substantial design effort expanded in its development, taken in light of appellants' arguments in the brief and reply brief, we cannot reasonably conclude that there is a significant nexus between the successes of the System 1000 and the touch screen input/output device *per se* required by the appealed claims. *See, e.g., Demaco Corp., supra.* Furthermore, even if it is held that appellants have established a

significant nexus between the successes of the System 1000 and the touch screen input/output device *per se* as claimed on this record, the substantial design of the System 1000 in both appearance and systems alone, none of which is claimed *per se*, establishes that the evidence is not commensurate in scope with the appealed claims which simply require only at least one of the certain means and/or units of a hemodialysis apparatus specified therein. *See In re Kulling*, 897 F.2d 1147, 1149-50, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990); *In re Dill*, 604 F.2d 1356, 1361, 202 USPQ 805, 808-09 (CCPA 1979); *In re Tiffin*, 488 F.2d 791, 792, 171 USPQ 294 (CCPA 1971)(evidence established commercial success and the satisfaction of long-felt need is limited to "cups" and the claims are drawn to "containers" broadly).

Accordingly, based on our consideration of the totality of the record before us, we have weighed the evidence of obviousness found in the combined teachings of Lichtenstein, Rubalcaba and Kerns with appellants' countervailing evidence of and argument for nonobviousness and conclude that the claimed invention encompassed by appealed claims 30 through 34, 37, 40 and 41 would have been obvious as a matter of law under 35 U.S.C. § 103(a).

The examiner's decision is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

CHUNG K. PAK)
Administrative Patent Judge)
)
)
)
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Administrative Patent Judge) APPEALS AND
) INTERFERENCES
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